IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Miri Seiberg, et al.

Serial No. 09/698,454

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Art Unit: 1617

Examiner: Y. Chong

Attorney Docket No.: JBP 518

Soy Depigmenting and Skin Care Compositions

DECLARATION OF MIRI SEIBERG, PH.D.

I, Miri Seiberg, am a Distinguished Research Fellow in the Skin Research Center at Johnson & Johnson Consumer Companies, Inc. My education includes a Ph.D. in Molecular Biology from The Weizmann Institute of Science, Rehovot, Israel, in collaboration with Princeton University, Princeton, NJ and a B. S. in Life Sciences from Tel-Aviv University, Tel-Aviv, Israel. My curriculum vitae is attached hereto as Exhibit A.

1. All protein molecules are composed of polypeptide chains of α-amino acids. Proteins are defined by both (1) their chemical structure, which includes its substituent amino acids as well as their unique conformation and (2) their biological function. A protein's biological function or activity requires the presence of both its chemical structure and conformation. [Biochemistry, A. L. Lehninger, 1975, p. 62- 66] (attached hereto as Exhibit B).

2. Proteins are said to be "denatured" when their physical and physiological properties are changed such that they lose their activity. Such change is generally due to a change in a protein's chemical structure and/or conformation. Protein denaturation and the consequent loss of biological activity are not related to the source of the protein or to their origin, and are described in biochemistry textbooks (e.g. Biochemistry, A. L. Lehninger, 1975, p.62-63).

3. Those knowledgeable about protein activity at the time the invention was made were aware that proteins are denatured in the presence of organic solvents. The effect of organic chemicals on protein denaturation has been studied for decades. A 1975 publication from Matveev describes the dependence of denaturation time on organic solvent concentrations. Extraction with organic solvents was shown to denature many proteins (Sikorski and Naczk, 1981). In 1984, Benedek et al measured the kinetics of denaturation of several proteins, including soybean trypsin inhibitor (STI), as a function of the organic modifier employed. Khmelnitsky et al (1991) documented the denaturation of several proteins by a broad series of organic solvents of different nature. van Erp et al (1991) had developed a theoretical model, based on a generally accepted notion that the destruction of the protein hydration shell is one of the main reasons for protein denaturation by organic solvents. These studies document that proteins (including STI) are denatured in the presence of organic solvents. The foregoing publications are attached hereto as Exhibit C.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Dr. Miri Seiberg

9/17/08

Date